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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,117	07/31/2003	Hilda Elizabeth Smith	2183-6055US	5350
24247	7590	06/10/2004	EXAMINER	
TRASK BRITT			FIELD, TAMMY K	
P.O. BOX 2550			ART UNIT	
SALT LAKE CITY, UT 84110			PAPER NUMBER	

1645

DATE MAILED: 06/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/632,117	<b>Applicant(s)</b> SMITH, HILDA ELIZABETH	
	<b>Examiner</b> Tammy K. Field	<b>Art Unit</b> 1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 December 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-8 are drawn to a process for modulating virulence of a *Streptococcus*, the first appearing technical feature.

Group II, claim(s) 9-10 are drawn to a process for assaying virulence of a *Streptococcus*, 2<sup>nd</sup> method of use of a polymeric material.

Group III, claim(s) 11-15 are drawn to an isolated or recombinant nucleic acid molecule, vector, host cell, and vaccine, 1<sup>st</sup> product/composition.

Group IV, claim(s) 16, 18, and 20 are drawn to a protein, antigen, and vaccine or diagnostic test, 2<sup>nd</sup> product/composition.

Group V, claim(s) 17 and 19 are drawn to an antibody and diagnostic test, 3<sup>rd</sup> product/composition.

2. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature of claim 1 is a process for modulating virulence of a *Streptococcus*. The art of Jadoun, J., *et al.* (Microbial Pathogen. 2000; 29: 311-317) teach transposon (Tn916) insertion and integration in *Streptococcus* resulting in reduced internalization efficiency (see Abstract). Jadoun, J., *et al.* also teach generation of clones having a modified genomic fragment of *Streptococcus* **capable** (emphasis added) of hybridizing to instant nucleotide sequences at page 312 (see Results and Discussion). Therefore, Unity of Invention is not fulfilled because

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there is not a technical feature that is “special”, in that the technical feature does not define a contribution over the art. As such, the process for modulating virulence of a Streptococcus comprising modifying a genomic fragment of Streptococcus lacks unity of invention with the processes set forth in Inventions of Group I (modulating virulence) and II (assaying virulence). Inventions III (nucleic acid), IV (protein), and V (antibody) do not require the use of the technical feature of Group I and since they define separate technical features as set forth supra, Inventions I-V lack unity of invention because they do not form a single general concept. Furthermore, different technical features in Inventions of Group III, IV, and V do not rely upon the technical feature of Group I and therefore also lack unity of invention because they lack a technical feature in common within the meaning of PCT Rule 13.2.

3. This application contains claims are directed to more than one species of the generic Invention of Group I. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1 and further under PCT Rule 13.2, the species lack the same or corresponding special technical features because each SEQ ID NO species would elicit a different molecular response for modulating virulence and therefore by definition do not meet the requirements of PCT Rule 13.2.

The species are as follows:

**Invention I** (Claim 1) NOTE: The examiner acknowledges each sequence listed below or fragments thereof.

A. SEQ ID NO: 8	J. SEQ ID NO: 17	R. SEQ ID NO: 26
B. SEQ ID NO: 9	K. SEQ ID NO: 18	S. SEQ ID NO: 27
C. SEQ ID NO: 10	L. SEQ ID NO: 19	T. SEQ ID NO: 28
D. SEQ ID NO: 11	M. SEQ ID NO: 20	U. SEQ ID NO: 29
E. SEQ ID NO: 12	N. SEQ ID NO: 21	V. SEQ ID NO: 30
F. SEQ ID NO: 13	O. SEQ ID NO: 22	W. SEQ ID NO: 31
G. SEQ ID NO: 14	P. SEQ ID NO: 23	X. SEQ ID NO: 32
H. SEQ ID NO: 15	Q. SEQ ID NO: 24	Y. SEQ ID NO: 33
I. SEQ ID NO: 16	R. SEQ ID NO: 25	Z. SEQ ID NO: 34

A.A. SEQ ID NO: 35	J.J. SEQ ID NO: 44
B.B. SEQ ID NO: 36	K.K. SEQ ID NO: 45
C.C. SEQ ID NO: 37	
D.D. SEQ ID NO: 38	
E.E. SEQ ID NO: 39	
F.F. SEQ ID NO: 40	
G.G. SEQ ID NO: 41	
H.H. SEQ ID NO: 42	
I.I. SEQ ID NO: 43	

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The following claim(s) are generic: 1, 7, 9, 11, 16, and 17.
5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). If applicant elect Invention I or V, they should also elect a species as set forth supra.
6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the

product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

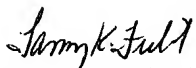
Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tammy K. Field whose telephone number is (571) 272-0856. The examiner can normally be reached on Monday-Friday from 7am-4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached at (571) 272- 0864.

Papers relating to this application may be submitted to Technology Center 1600 Group 1640 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communications and After Final communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Tammy K. Field  
June 8, 2004

  
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